Proposed Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N)

Decision Summary

CMS proposes coverage for Transcutaneous Electrical Nerve Stimulation (TENS) for chronic low back pain (CLBP) only when all of the following conditions are met.

A. For the purposes of this decision CLBP is defined as:

a. an episode of low back pain that has persisted for three months or longer; and

b. is not the result of certain well-defined diseases that may contribute to low back pain but which are not primarily low back syndromes.

For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom. Certain systemic diseases, e.g. rheumatoid arthritis, multiple sclerosis etc, manifest many debilitating symptoms of which low back pain is not the primary focus. We believe that the appropriate management of these types of diseases is guided by a systematic strategy aimed at the underlying causes. While TENS may infrequently be used adjunctively in managing the symptoms of these diseases, it is clearly not the primary therapeutic approach.

B. The patient is enrolled in a prospective clinical study that addresses one or more aspects of the following questions in a randomized, controlled design using validated and reliable instruments. This can include randomized crossover designs.

1. Does the use of TENS provide a clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?

2. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?
3. Does the use of TENS provide a clinically meaningful reduction in other medical treatments or services used in the medical management of CLBP?

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the clinical study is to test whether TENS potentially improves the participants' health outcomes.
b. The clinical study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The clinical study does not unjustifiably duplicate existing studies.
d. The study design is appropriate to answer the research question being asked in the study.
e. The clinical study is sponsored by an organization or individual capable of successfully executing the proposed study.
f. The clinical study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
g. All aspects of the clinical study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
h. The clinical study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
i. The clinical study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
j. The clinical study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
k. The clinical study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors

   (http://www. icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

l. The clinical study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The clinical study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

We are requesting public comments to this proposed decision pursuant to section 1862(l) of the Social Security Act (the Act). After consideration of the public comments and any additional evidence, we will issue a final determination responding to the public comments consistent with §1862(l)(3) of the Act.

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